

Message Text

UNCLASSIFIED

PAGE 01 BERN 02717 070846Z
ACTION HEW-06

INFO OCT-01 EUR-12 ISO-00 OES-07 MED-03 /029 W

-----092879 070912Z /20

P 070755Z JUN 78

FM AMEMBASSY BERN

TO SECSTATE WASHDC PRIORITY 6393

INFO AMEMBASSY VIENNA PRIORITY

AMEMBASSY COPENHAGEN PRIORITY

AMEMBASSY PARIS PRIORITY

AMEMBASSY BONN PRIORITY

AMEMBASSY LONDON PRIORITY

AMEMBASSY THE HAGUE PRIORITY

AMEMBASSY OSLO PRIORITY

AMEMBASSY MADRID PRIORITY

AMEMBASSY ROME PRIORITY

AMEMBASSY STOCKHOLM PRIORITY

AMCONSUL ZURICH POUCH

UNCLAS BERN 2717

39 11652: N/A

TAGS: OGEN, EIND, TBIO, XG

SUBJ: FDA ADVISORY - DEFECTIVE INTRA-AORTIC BALLOON PUMPS

(RECALL T-098-8)

REF: STATE 138793 NOTAL

1. EMBASSY HAS CONTACTED SWISS CONSIGNEES LISTED IN REFTEL AS WELL AS AMERICAN COMPANY'S AGENT, KONTRON AG OF ZURICH. KONTRON INFORMED US THAT ONLY ONE MODLE 10 AVCO BALLOON PUMP IN OPERATION IN SWITZERLAND (KANTONSSPITAL ZURICH) AND THAT UNIT RETROFITTED BEGINNING MAY. CENTRE HOSPITALIER UNIVERSITAIRE VAUDOIS IN LAUSANNE, ALSO CITED IN REFTEL, USED MODEL 7.

2. JONTRON ACTS AS EXCLUSIVE AGENT FOR AVCO ALSO IN UNCLASSIFIED

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PAGE 02 BERN 02717 070846Z

AUSTRIA, BELGIUM, DENMARK, FRANCE, W. GERMANY, BRITAIN, ITALY, HOLLAND, NORWAY, SPAIN, AND SWEDEN. WHEN KONTRON ZURICH WAS INFORMED APRIL 12 OF MODEL 10'S MALFUNCTIONING, SWISS FIRM IMMEDIATELY ALERTED ITS SUBAGENTS IN AFORE-MENTIONED COUNTRIES. DURING MAY REGROFIT COMPONENTS WERE SUPPLIED WHERE APPROPRIATE.

3. KONTRON PERPLEXED BY LIST OF COUNTRIES AND NAMES OF CLINICS SUBMITTED BY FDA. SWISS FIRM CLAIMS NO NUMBER MODEL 10S SUPPLIED TO BELGIUM OR SWEDEN AT ALL AND NONE TO A NUMBER OF INDIVIDUAL HOSPITALS LISTED. OTHERS, WHICH DID RECEIVE DEFECTIVE UNITS, WERE OMITTED FROM LIST. CASE IN POINT IS MEDIZINISCHE KLINIK IN GOETTINGEN, W. GERMANY. WARNER

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NNN

Message Attributes

Automatic Decaptoning: X
Capture Date: 01 jan 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: PUMPS, FOOD & DRUG REGULATIONS
Control Number: n/a
Copy: SINGLE
Draft Date: 07 jun 1978
Decaption Date: 01 jan 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 jan 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1978BERN02717
Document Source: CORE
Document Unique ID: 00
Drafter: n/a
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D780237-0669
Format: TEL
From: BERN
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1978/newtext/t19780688/aaaacxmm.tel
Line Count: 69
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: 7f4d5e90-c288-dd11-92da-001cc4696bcc
Office: ACTION HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 2
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: 78 STATE 138793
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 29 mar 2005
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: N/A
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 2461379
Secure: OPEN
Status: NATIVE
Subject: FDA ADVISORY - DEFECTIVE INTRA-AORTIC BALLOON PUMPS (RECALL T-098-8)
TAGS: OGEN, EIND, TBIO, XG
To: STATE
Type: TE
vdkvgwkey: odbc://SAS/SAS.dbo.SAS_Docs/7f4d5e90-c288-dd11-92da-001cc4696bcc
Review Markings:
Sheryl P. Walter
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